



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

FEB 24 2000 1734 '00 FEB 29 P2:11

Ms. Gloria S. Donovan
Legal Assistant
Metagenics, Inc.
100 Avenida La Pata
San Clemente, California 92673

Dear Ms. Donovan:

This is in response to your letter of February 1, 2000 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Metagenics, Inc. is making the following claims, among others, for the following products:

CoQ10-ST™

“...maintain healthy blood pressure”

Lipotain™

“...support healthy cholesterol...levels”

“...maintain health cholesterol ...levels”

SuperGarlic 6000™

“Helps support healthy cholesterol levels...”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to treat, prevent, or mitigate diseases, namely hypertension and hypercholesterolemia. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

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Please contact us if we may be of further assistance.

Sincerely,

John B. Foret, Ph.D.
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling,
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, San Francisco District Office, Office of Compliance, HFR-PA140

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (r/f, file)

HFS-810 (r/f)

HFS-800 (file)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-605

HFV-228 (Benz)

GCF-1 (Dorsey, Barnett, Nickerson)

f/t:HFS-456:rjm:2/23/00:docname:69168.adv:disc44



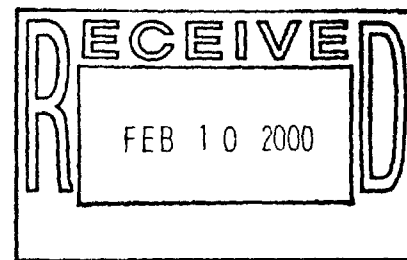
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100 Avenida La Pata, San Clemente, CA 92673 Tel: 949-366-0818/800-692-9400

February 1, 2000

Office of Special Nutritionals
Center for Food Safety And Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington, DC 20204

Certified Mail
Return Receipt



Re: Structure Function Claims/FDA Notification

Dear Sir or Madam:

Enclosed please find an original and two copies of the above document prepared in accordance with the proposed regulation 21 C.F.R. Section 101.93.

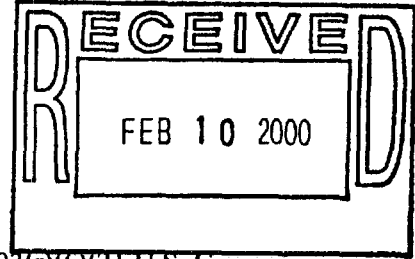
Should you have any questions or comments, please do not hesitate to contact Beverly Chin or me at the above number.

Sincerely,

Gloria S. Donovan
Legal Assistant

Enclosure

cc: Beverly Chin, Esq.



Notice is hereby given pursuant to the requirements of section 403(r)(6)(21 U.S. C. 343(r)(6) of the Federal Food, Drug, and Cosmetic Act and in accordance with the requirements of 21 CFR 101.93, that Metagenics, Inc. with its principal place of business at 100 Avenida la Pata, San Clemente, California 92673, (949) 366-0818, has commenced marketing the following dietary supplements bearing the following statement(s) on the label and/or in the labeling:

METAGENICS BRAND

Name of Supplement	Name of Ingredient or Supplement that is Subject to the Claim	Text of Claim
Arthrogen™	Niacin; N-Acetylcysteine	<p>Features a synergistic blend of N-acetylcysteine (NAC) and niacinamide in a formula designed to support the optimal function and health of joints.</p> <p>Preventing free radical damage is essential in promoting healthy tissues of the joint, including joint cartilage and synovial fluid. Maintaining the health of these tissues promotes healthy joint lubrication, flexibility, and function.</p> <p>NAC supports healthy joints through its potent antioxidant properties and through inhibition of cytokines.</p> <p>Niacinamide supports healthy joint function by inhibiting NF-kappaB, TNF-alpha, and poly (ADP-ribose) synthetase (PARS). Inhibition of PARS is associated with joint tissue</p>

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		tract.
ChondroCare™	Vitamin C; Zinc; Selenium; Copper Manganese; Glucosamine Sulfate; Chondroitin Sulfate	<p>A comprehensive formula designed to support healthy joints by featuring glucosamine sulfate and chondroitin sulfate.</p> <p>Glucosamine is the basis for the formation of vital connective tissue substances such as proteoglycans and glycosaminoglycans (GAGs). Chondroitin sulfate supports healthy joint matrix formation.</p> <p>ChondroCare also features the valuable mineral synergists zinc, copper, manganese, and selenium for added support of joint tissues.</p>
CoQ10-ST-100™	Coenzyme Q10	<p>CoQ10 is a naturally occurring substance that is essential for energy production and is of particular importance in the maintenance of cardiovascular health.</p> <p>CoQ10 has potent antioxidant properties and cell membrane stabilizing effects and may help maintain healthy blood pressure.</p>
Gastrogen™	Poria fungus; Job's Tears Seed; Pueraria Root; Saussurea Root; Patchouli Leaf; Angelica Dahurica Root; Atractylodes Rhizome; Fermented Leaven; Rice Sprouts; Chrysanthemum Flower; Gastrodia Rhizome; Tangerine Peel; Peppermint Leaf; Trichosanthes Root	<p>A Chinese herbal formula traditionally used to cool excess "stomach fire" element, supporting healthy digestive function after eating or drinking too much.</p>
Glutagenics™	Glutamine; Deglycyrrhizinized Licorice (dgl); Aloe Leaf Extract	<p>Features three key ingredients that comprehensively support the integrity and optimal function of the gastrointestinal lining.</p> <p>A healthy intestinal lining is essential for proper digestion,</p>

		<p>immune function, liver function, and overall health, primarily through its role as a barrier preventing the absorption of unwanted molecules.</p> <p>Glutagenics supplies:</p> <ul style="list-style-type: none"> - 3.5 grams of the amino acid glutamine, which provides both a source of fuel and precursors for growth to the rapidly dividing cells of the intestinal lining. - A concentrated extract of DGL, which promotes optimal gut mucosal integrity - A premium extract of aloe leaf, which promote a healthy intestinal lining.
Lipotain™	Niacin; Guggul Resin Extract	<p>Designed to support healthy cholesterol triglyceride, and lipoprotein(a) levels by supplying 500mg of inositol hexanicotinate per tablet.</p> <p>Guggul resin may help maintain healthy cholesterol and triglyceride levels.</p>
Mg/K Aspartate	Magnesium; Potassium	<p>Magnesium plays an important role in normal growth, development, and energy production, and potassium is a key electrolyte in cellular function.</p>
Ultra CLA™	Conjugated Linoleic Acid; Rosemary Leaf Extract	<p>Rosemary has potent antioxidant properties.</p> <p>CLA is a naturally occurring fatty acid that may support healthy glucose and insulin metabolism through its activation of nuclear receptors that are potent insulin sensitizers.</p> <p>By enhancing insulin sensitivity and glucose uptake,</p>


METABOTANICA BRAND

Name of Supplement	Name of Ingredient or Supplement that is Subject to the Claim	Text of Claim
HcpataPlex™	Gentian Root; Bupleurum root; Alisma root; Rehmannia Root; Baical Skullcap; Gardenia Fruit; Knotweed Aerial Parts; Plantago Seed; Dong Quai Root; Licorice Root	Combines herbs traditionally used in China for centuries to support liver detoxification and balance.
Serenagen™	Rhemanian root; Schizaandra Fruit ; Jujube Fruit; Dong Quai Root; Asparagus Root; Ophiopogon Root; Schophularia Root; Codonopsis Root; Salvia Root; Poria Sclerotium; Polygala Root; Platycodon Root	A classic Chinese herbal formula traditionally used to help the body adapt to stress
SuperGarlic 6000™	Raw Garlic Concentrate; Calcium; Phosphorus	Garlic helps support healthy cholesterol levels and a healthy cardiovascular and immune system.
Tran-Q™	Polygala Root; Biota Seed; Platycodon Root; Rehmannia root; Citrus Peel; Jujube Fruit; Locorice root; Job's Tears Seed ; Poria Fungus; Altractylodes Rhizome; Gardenia Fruit	A time-honored formula that has been traditionally used to maintain a calm spirit and quiet the heart.
VascuTone™	Hawthorn Berry; Arjuna Bark; Coleus Forskohlii Root Extract; Pushkarmool Root; Guggul Resin	<p>A comprehensive cardiovascular herbal formula that features premium standardized extracts of hawthorn berry and a variety of Ayurvedic herbs traditionally used to support the heart.</p> <p>Hawthorn is a popular herb traditionally used to help promote circulation and overall cardiovascular function, possibly by helping to maintain healthy blood pressure and blood vessel dilation.</p>

VenaPlex™	Rutin; Horse Chestnut Seed Extract; Arjuna Bark 8:1 Extract; Coleus Forskohlii Root Extract; Inula Racemosa Extract; Guggul Resin 5:1 Extract	<p>Features a premium standardized extract of horse chestnut seed, an herb widely used to help promote venous tone and capillary integrity.</p> <p>Horse chestnut is combined with rutin, a powerful flavonoid that helps maintain capillary integrity, and standardized extract of select Ayurvedic herbs traditionally used to help support a healthy cardiovascular system.</p>
Yin Essence™	Rehmannia Root Prepared; Dioscorea Root; Cornus Fruit; Tree Peony Root-Bark; Poria Fungus; Alisma Root; Schizandra Berry	<p>A time-honored formula traditionally used to nourish and support kidney "yin".</p> <p>Traditional Chinese herbology considers the kidney to be the source of all bodily fluids that promote vitality.</p>

THE UNDERSIGNED CERTIFIES THAT THE INFORMATION CONTAINED IN THIS NOTICE IS COMPLETE AND ACCURATE AND THAT METAGENICS, INC. HAS SUBSTANTIATION THAT THE STATEMENTS CONTAINED HEREIN ARE TRUTHFUL AND NOT MISLEADING.

Date January 27, 2006

BY: 
Kim Krumhar, Ph.D.
Its Director of Research and Development